



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/631,709	08/03/2000	Satoshi Koizumi	766.37	9510

5514 7590 01/14/2003

FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER

SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
----------	--------------

1651

DATE MAILED: 01/14/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/631,709

Applicant(s)
Kolzumi et al.

Examiner
Sandra Saucier

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 1, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-7, 9-22, and 24-34 is/are pending in the application.
- 4a) Of the above, claim(s) 6, 7, 18, 19, 21, 22, 33, and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 9-17, 20, and 24-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8 6) ☐ Other: _____

Art Unit: 1651

DETAILED ACTION

Claims 1-3, 5-7, 9-22, 24-34 are pending. Claims 1-3, 5, 9-17, 20, 23-32 are considered on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3, 24-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/068528. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same process of generating GDP-4-keto-6-deoxymannose.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. This rejection will be reassessed at time of allowance.

Art Unit: 1651

Claim Rejections – 35 USC § 102

Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 99/36555 [IDS] or EP 870 841 [IDS].

The claims are directed to a process of making GDP fucose by allowing GDP-4-keto-6-deoxymannose and an enzyme source derived from a microorganism, which is capable of converting the GDP-4-keto-6-deoxymannose to GDP fucose and recovering the GDP fucose therefrom.

The references are relied upon as explained below.

WO 99/36555 discloses a process of making GDP fucose using mannose, GTP and GDP-4-keto-5-deoxymannose 3,5-epimerase/GDP-4-keto-6-galactose reductase. The enzyme is derived from recombinant microbes.

The epimerase/reductase activity is the same as disclosed as being useful on page 6, (16) of the specification, the substrates/intermediates of mannose the same as disclosed on page 4, (6) of the specification and in Figure 16 of the reference, where the schematic of mannose conversion to GDP mannose which is converted to GDP-4-keto-6-deoxymannose and to GDP-fucose is shown. Example 7, page 52 of '555 demonstrates the conversion of GDP mannose to GDP-4-keto-6-deoxymannose to GDP-fucose and recovery of GDP-fucose. Enzymes are used which are microbially derived and can be interpreted to fall within the phrase "a concentrated product of a culture broth" and other products of the microbe as recited in the claims.

EP 870 841 teaches in Example 16, the process of producing GDP-fucose by incubating various recombinant cells with GMP and mannose as well as other components. GDP-fucose is recovered. A cell containing gmd and wcaG genes which converts GDP-mannose to GDP-4-keto-6-deoxymannose is included in the mixture.

Claims 2, 10, 13-15, 17 and 20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 99/36555 [IDS] or EP 870 841 [IDS].

The claims are directed to a process of making GDP fucose by allowing a GTP precursor, a saccharide and enzyme sources capable of forming GDP-4-keto-6-mannose and converting the GDP-4-keto-6-deoxymannose to GDP

Art Unit: 1651

fucose and recovering the GDP fucose therefrom.

WO 99/36555 disclose in Fig. 16 and elsewhere that GDP, which is a precursor of GTP, a saccharide such as mannose or glucose when incubated with an enzyme source in a medium forms GDP-4-keto-6-deoxymannose which is converted to GDP fucose. In Figure 16, the GDP-fucose is shown to be further used to fucosylate a substrate; however, on page 29, line 3 and other places, recovery of the GDP-fucose is clearly explained.

EP 870 841 discloses a process for production of GDP fucose, example 16. A GTP precursor (GMP) and a saccharide (mannose) are incubated with enzyme sources which produce GDP-fucose via GDP-4-keto-6-mannose.

These disclosures clearly anticipate the present invention as claimed.

Claim Rejections - 35 USC § 103

Claims 1, 2, 5, 9-17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/36555 [IDS] in combination with EP 870 841 [IDS].

The claims are directed to an enzymatic process of making GDP fucose by allowing a GTP precursor, a saccharide and enzyme sources to produce GTP and then using the GTP to form GDP-4-keto-6-deoxymannose, converting the GDP-4-keto-6-deoxymannose to GDP fucose and recovering the GDP fucose therefrom.

The references are relied upon as explained below.

WO 99/36555 disclose in Fig. 1 and on page 2 that GDP mannose is provided and is converted to GDP fucose.

EP 870 841 teaches a process of producing sugar nucleotides from a sugar and a nucleotide precursor (page 5, l. 25) using recombinant microbes. In particular, in the production of GDP-mannose, example 14, GMP (nucleotide precursor) and mannose (sugar) are present in the incubation medium with *C. ammoniagenes*. On page 5, it is particularly disclosed that the use of expensive starting materials such as nucleotide triphosphates (GTP) are not necessary and that use of a sugar and a nucleotide precursor can be used in the production of, as in example 16, GDP-fucose. Microbes may be *E. coli* or *Corynebacterium*

Art Unit: 1651

ammoniagenes (page 5, l. 25-49, page 9, l. 51-57)).

The addition of the method steps of EP 870 841 to the method of WO 99/36555 would have been obvious particularly in light of the direct suggestion on page 5 of '841 to generate GTP for use in the production of GDP-fucose from mannose and GMP as shown in example 16. This manner of production of GTP which can be usefully incorporated into other processes is well known in the art (page 18, l. 18 and l. 27).

Claims 3, 24-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO99/09180 [N] in combination with EP 870 841 [IDS].

The claims are directed to the production and recovery of GDP-4-keto-6-deoxymannose using enzyme sources and a GTP precursor and a saccharide.

WO 99/09180 discloses a method of producing GDP-4-keto-6-deoxymannose from GDP-mannose using an enzyme source (dehydratase) present in recombinant *E. coli* (Example 11). The GDP-4-keto-6-deoxymannose is recovered.

The reference lacks the use of a GTP precursor (GMP) and a saccharide (mannose) as the starting materials to make the GDP-mannose starting material of the reference.

EP 870 841 teaches a process of producing sugar nucleotides from a sugar and a nucleotide precursor (page 5, l. 25) using recombinant microbes. In particular, in the production of GDP-mannose, example 14, GMP (nucleotide precursor) and mannose (sugar) are present in the incubation medium with *C. ammoniagenes*. On page 5, it is particularly disclosed that the use of expensive starting materials such as nucleotide triphosphates (GTP) are not necessary and that use of a sugar and a nucleotide precursor can be used in the production of GDP-mannose. Microbes may be *E. coli* or *Corynebacterium ammoniagenes* (page 5, l. 25-49, page 9, l. 51-57)).

The addition of the method steps of EP 870 841 to the method of WO 99/09180 would have been obvious particularly in light of the direct suggestion on page 5 of '841 to generate GTP for use in the production of GDP-saccharides from mannose and GMP. This manner of production of GTP which

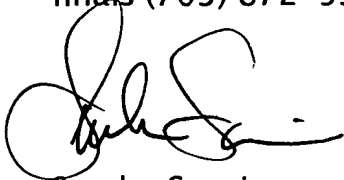
Art Unit: 1651

can be usefully incorporated into other processes is well known in the art (page 18, l. 18 and l. 27).

One of ordinary skill in the art would have been motivated at the time of invention to make this addition to the method in order to obtain the resulting compound as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30AM to 5:00PM Monday and Tuesday and 8:30-noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.



Sandra Saucier
Primary Examiner
Art Unit 1651
December 20, 2002